

REMARKS

Reconsideration of the rejections set forth in the Office Action dated June 28, 2001 and entry of the present amendment are respectfully requested. In response to the Office Action, claims 1, 2, 4-6, 8, 10 and 11 have been amended without prejudice to more particularly and distinctly set forth the patentable subject matter of the present invention. Please note that on the "Office Action Summary" page of the Office Action (PTO-326 of Paper No. 6), both "final" and "non-final" statuses have been marked. However, the Office Action is the first Office Action, and the Examiner has confirmed to Applicant's attorney Jura Zibas that the Office Action is non-final.

Claims 1-14 and 17 are currently pending in this matter.

Rejections Under 35 U.S.C. §112

Claims 1, 4, 6, 8, 10, and 11 have been rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner asserted that claims 1 and 4 recite a variable Y which also includes the term "epoxide;" claims 6 and 8 do not end in a period; and claims 10 and 11 both recite R3 at the C9 position when it should be R4 at that position.

Without acquiescence in the Examiner's reasons for the rejections, Applicant has deleted the term "epoxide" in claims 1 and 4. Similarly, claims 6, 8, 10, 11 have been amended as suggested by the Examiner. Therefore, Applicant respectfully submits that the rejections have been obviated.

In addition, the Examiner has rejected claims 1-14 and 17 on the basis that the invention appears to employ a novel marine bacterium that is essential to the claimed invention. The Examiner alleges that the specification does not disclose a repeatable process to obtain the microorganism and therefore requires that the microorganism be deposited in accordance with 37 C.F.R. 1.081-1.809.

Applicant respectfully submits that the bacterium was deposited at the ATCC, as indicated in the description at page 7, lines 10 and 11. In addition, the Specification describes

how naturally occurring members of the claimed class of compounds (Basiliskamides A & B) were initially isolated from the bacterium, and also teaches a repeatable synthetic method for preparation of the compounds and analogs thereof (see pages 15 and 16 of Specification). Furthermore, page 5, lines 19-21 of the Specification discloses that naturally occurring compounds of the invention could be obtained from a natural source, or synthesized as described in the specification. Therefore, a repeatable method for obtaining the bacterium is not necessary to enable the invention.

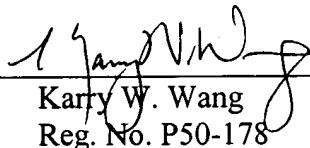
In view of the foregoing, it is submitted that all of the stated grounds of rejection have been properly traversed, and that the application is fully in condition for allowance. A notice to that effect is earnestly solicited.

The Examiner is invited to telephone the undersigned representative if it is believed that an interview may be useful for any reason.

Respectfully submitted,

Pillsbury Winthrop, LLP

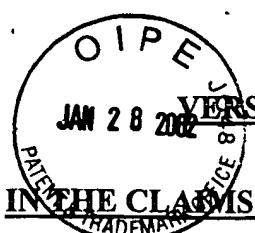
Date: December 28, 2001

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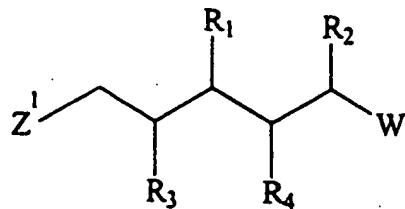
APPENDIX

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The specification is changed as follows (text which has been struck through has been deleted and underlined text _____ has been added):

1. (Amended) A compound or a physiologically acceptable salt thereof, wherein the compound has the formula:



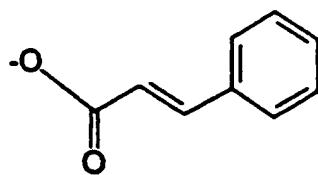
wherein:

R₁ and R₂ are the same or different and are independently H or R;

R is a structural fragment having a saturated or unsaturated linear, branched, or cyclic, skeleton containing one to ten carbon atoms in which the carbon atoms may be optionally substituted with a substituent selected from the group consisting of: -OH; =O; -OR₅; -O₂CR₅; -SH; -SR₅; -SOCR₅; -NH₂; -NHR₅; -NH(R₅)₂; -NHCOR₅; NRCOR₅; -I; -Br; -Cl; -F; -CN; -CO₂H; -CO₂R₅; -CHO; -COR₅; -CONH₂; -CONHR₅; -CON(R₅)₂; -COSH; -COSR₅; -NO₂; -SO₃H; -SOR₅; and -SO₂R₅, wherein R₅ is a linear, branched or cyclic, one to ten carbon saturated or unsaturated alkyl group;

R₃ and R₄ are different and are independently selected from the groups consisting of OH,

(a)



and



wherein,

Z^1 and Z are linear or branched, saturated or unsaturated, one to ten carbon fragments optionally substituted with Y ;

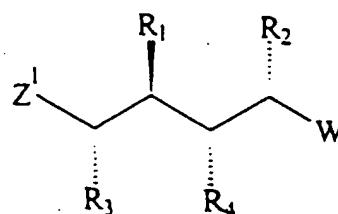
Ar is a monocyclic, bicyclic or tricyclic, fully or partially aromatic system containing five or six membered carbocyclic or, oxygen, nitrogen or sulphur containing heterocyclic rings, optionally substituted with R or Y ;

Y is selected from the group consisting of: H ; $=\text{O}$; $-\text{OH}$; $-\text{OR}$; $-\text{O}_2\text{CR}$; $-\text{SH}$; $-\text{SR}$; $-\text{SO}\text{CR}$; $-\text{NH}_2$; $-\text{NHR}$; $-\text{NH}(\text{R})_2$; $-\text{NHCOR}$; NRCOR ; $-\text{I}$; $-\text{Br}$; $-\text{Cl}$; $-\text{F}$; $-\text{CN}$; $-\text{CO}_2\text{H}$; $-\text{CO}_2\text{R}$; $-\text{CHO}$; $-\text{COR}$; $-\text{CONH}_2$; $-\text{CONHR}$; $-\text{CON}(\text{R})_2$; $-\text{COSH}$; $-\text{COSR}$; $-\text{NO}_2$; $-\text{SO}_3\text{H}$; $-\text{SOR}$; $-\text{SO}_2\text{R}$; and, $-\text{O-}(\text{epoxide})$;

W is H or R ;

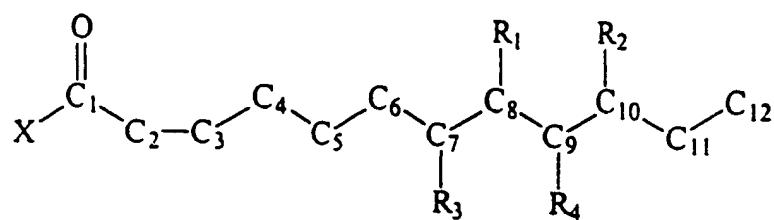
with the provisos that when W is H , R_2 is not H ; when R_2 is CH_3 , W is not n-propyl; and, one of R_3 and R_4 is (a) or (b) and another of R_3 and R_4 is OH .

2. (Amended) The compound or physiologically acceptable salt thereof of claim 1 having the stereoisomeric form: I.



I

4. (Amended) A compound or a physiologically acceptable thereof, wherein the compound has the formula:



wherein:

a single, double or triple bond exists between one or more of: C-2 and C-3; C-3 and C-4; C-4 and C-5; and, C-5 and C-6;

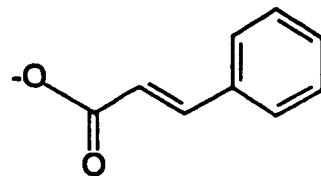
X is NH₂, NHR, NR₂, OH, OR, SH, SR, H, or CF₃;

R is a structural fragment having a saturated or unsaturated linear, branched, or cyclic, skeleton containing one to ten carbon atoms in which the carbon atoms may be optionally substituted with a substituent selected from the group consisting of: -OH; =O; -OR₅; -O₂CR₅, -SH; -SR₅; -SOCR₅; -NH₂; -NHR₅; -NH(R₅)₂; -NHCOR₅; NRCOR₅; -I; -Br; -Cl; -F; -CN; -CO₂H; -CO₂R₅; -CHO; -COR₅; -CONH₂; -CONHR₅; -CON(R₅)₂; -COSH; -COSR₅; -NO₂; -SO₃H; -SOR₅; and -SO₂R₅, wherein R₅ is a linear, branched or cyclic, one to ten carbon saturated or unsaturated alkyl group;

R₁ and R₂ are the same or different and are independently H or R;

R₃ and R₄ are different and are selected from the group consisting of: OH,

(a)



and

(b)



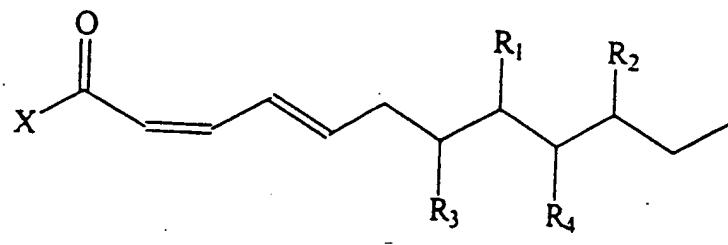
wherein, Z is a linear or branched, saturated or unsaturated, one to ten carbon fragment optionally substituted with Y;

Ar is a monocyclic, bicyclic or tricyclic, fully or partially aromatic system containing five or six membered carbocyclic or, oxygen, nitrogen or sulphur containing heterocyclic rings, optionally substituted with R or Y;

Y is selected from the group consisting of: H; =O; -OH; -OR; -O₂CR; -SH; -SR; -SO₂CR; -NH₂; -NHR; -NH(R)₂; -NHCOR; NRCOR; -I; -Br; -Cl; -F; -CN; -CO₂H; -CO₂R; -CHO; -COR; -CONH₂; -CONHR; -CON(R)₂; -COSH; -COSR; -NO₂; -SO₃H; -SOR; -SO₂R; and, -O- (epoxide);

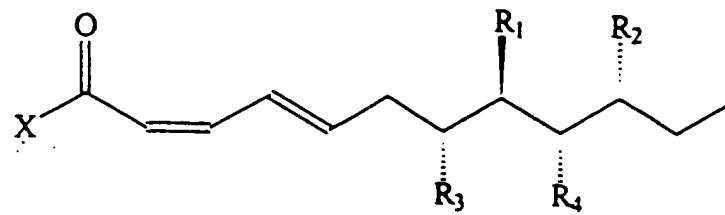
with the proviso that one of R₃ and R₄ is (a) or (b), and another of R₃ and R₄ is OH.

5. (Amended) The compound or physiologically acceptable salt thereof of claim 4 having the structure: II.



II

6. (Amended) The compound or physiologically acceptable salt thereof of claim 4, having the structural and stereoisomeric form: III



III

8. (Amended) The compound or physiological salt thereof of claim 4, wherein R₃ is (a).

10. (Amended) The compound or physiological salt thereof of claim 4, wherein R₃ at C₇ is (a) and R₃R₄ at C₉ is OH.

11. (Amended) The compound or physiological salt thereof of claim 4, wherein R₃ at C₇ is OH and R₃R₄ at C₉ is (a).

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